

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
NORTHERN DIVISION

ADAM KANUSZEWSKI and ASHLEY
KANUSZEWSKI as parent-guardians and
next friend to their minor children,
D.W.L., R.F.K., and C.K.K.; SHANNON
LAPORTE,
as parent-guardian and next friend to her
minor children, M.T.L. and E.M.O.; and
LYNNETTE WIEGAND, as parent-
guardian and next friend to her minor
children, L.R.W., C.J.W., H.J.W., and
M.L.W.,

No. 18-cv-10472

HON. THOMAS L. LUDINGTON

MAG. JUDGE PATRICIA T.
MORRIS

**STATE DEFENDANTS’
REPLY BRIEF**

Plaintiffs,

v

MICHIGAN DEPARTMENT OF
HEALTH AND HUMAN SERVICES;
NICK LYON, sued in his official and
individual capacities; DR. SANDIP
SHAH, sued in his official and individual
capacities; DR. SARAH LYON-CALLO,
sued in her official and individual
capacities; HARRY HAWKINS, sued in
his official and individual capacities;
MARY KLEYN, sued in her official and
individual capacities; MICHIGAN
NEONATAL BIOBANK, INC also
known as MICHIGAN NEONATAL
BIOREPOSITORY; DR. ANTONIO
YANCEY, sued in his official and
individual capacities,

Defendants.

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**STATE DEFENDANTS' REPLY BRIEF IN SUPPORT OF
MOTION TO DISMISS FIRST AMENDED COMPLAINT BASED ON
FEDERAL RULES OF CIVIL PROCEDURE 12(b)(1) AND 12(b)(6)**

ARGUMENT

Plaintiffs' First Amended Complaint (Complaint) advances a first-time, flawed constitutional challenge to Michigan's newborn screening program (NBS), a program that: (1) Michigan has operated successfully for over 50 years; (2) is similarly conducted in all 50 states; and (3) the federal government supports both legally and financially. Critically, no court has ever held, as Plaintiffs now contend, that Michigan's or another State's NBS program violates the U.S. Constitution's Fourth Amendment protection against unreasonable searches and seizures or one of the limited "liberty interests" protected by the Fourteenth Amendment. To the contrary, Courts have dismissed comparable cases for lack of standing, see *Higgins v. Texas Dep't of Health Servs.*, 801 F. Supp. 2d 541 (W.D. Tex. 2011) and *Doe v. Adams*, 53 N.E.3d 483 (Ind. Ct. App. 2016), or expressly upheld the State's NBS program against similar constitutional challenges, see *Spiering v. Heineman*, 448 F. Supp. 2d 1129 (D. Neb. 2006) and *Douglas County v. Anaya*, 694 N.W.2d 601 (Neb. 2005), *cert. denied Anaya v. Douglas County*, 546 U.S. 826 (2005). The Court should rule likewise here, dismissing with prejudice Plaintiffs' claims against State Defendants.

Plaintiffs' Response fails to address or correct the numerous deficiencies in their Complaint, subjecting it to dismissal under Federal Rule of Civil Procedure 12(b)(1) (lack of subject-matter jurisdiction due to immunity and no standing) and

Rule 12(b)(6) (failure to state a viable §1983 claim based on violation of any recognized constitutional right—as to both the claims against State Defendants individually and in their official capacities for *Ex parte Young* prospective injunctive relief). Specifically, Plaintiffs’ Complaint focuses on (and Response further illustrates) their chief complaint, which is that the NBS statute, Mich. Comp. Laws § 333.5431, requires testing without prior parental consent and State Defendants have complied with that law. (*See, e.g.*, R. 45, Pl.’s Resp. Brf., Pg. ID# 701 (“But the problem is clear: the entire Newborn Screening Program (NSP) forgot to include a major legal and constitutional obligation—consent.”) (emphasis in original).) Notwithstanding their Response’s attempts to salvage (and amend) the Complaint, Plaintiffs’ pled claims are defective and must be dismissed for the following, non-exclusive reasons:

- Because no court has ever held Michigan’s (or another State’s) NBS program unconstitutional, the State Defendants have not violated any “clearly established” federal right. *Barker v. Goodrich*, 649 F.3d 428, 433 (6th Cir. 2011). Accordingly, all claims against State Defendants in their individual capacities are subject to dismissal based on qualified immunity, and Plaintiffs are not entitled to any discovery on these claims. *Mitchell v. Forsyth*, 472 U.S. 511, 526 (1985) (“Unless the plaintiff’s allegations state a claim of violation of clearly established law, a defendant pleading qualified immunity is entitled to dismissal before the commencement of discovery.”).
- Plaintiffs’ real challenge is to Michigan’s NBS statute, Mich. Comp. Laws § 333.5431, and its lack of prior parental consent when these nine children were tested. As explained in State Defendants’ Brief, however, the initial heel stick was reasonable under the Fourth Amendment (if it even constitutes a search), as was the subsequent storage. Moreover, declaratory and prospective injunctive relief—

which is the only relief Plaintiffs can seek against the State Defendants under *Ex parte Young*—is inappropriate here because the nine Plaintiff children will not be subject to newborn screening again and their parents can destroy their stored blood samples at any time.

- Plaintiff's Response posits an unsupported interpretation and limitation on the holding in *Jacobson v. Massachusetts*, 197 U.S. 11, 38 (1905), which broadly held that compulsory vaccination laws with only medical exemptions do not violate any federal constitutional right. *See also Nikolao v. Lyon*, 875 F.3d 310, 316 (6th Cir. 2017). Contrary to Plaintiffs' assertions, nothing in *Jacobson* or its progeny limits the state's police power to only emergency situations or communicable diseases.
- The proper Plaintiffs in this case according to the Complaint are the nine Plaintiff children, not their parents who according the caption bring claims solely "as parent-guardians and next friend to their minor children." (R. 26, 1st Am. Compl., Pg. ID# 300.) Thus, leave to amend is required for the parents to pursue their own claims, and in any event would be futile because—similar to the asserted Plaintiff children's rights—the parents have no absolute right to make potentially harmful medical decisions on behalf of their children. *See, e.g., Jacobson*, 197 U.S. at 38 (mandatory vaccinations); *Nikolao* 875 F.3d at 316 (same); *Prince v. Massachusetts*, 321 U.S. 158 (1944) (child labor laws); *Spiering v. Heineman*, 448 F. Supp. 2d 1129 (D. Neb. 2006) (mandatory newborn screening).
- Because parental consent to NBS testing is not a constitutional requirement, Michigan's no-consent statute is constitutional. If Plaintiffs wish to pursue their admitted goal of amending the statute to include exemptions to testing or to require absolute, prior parental consent, they must address these public policy arguments that are open to debate to the Michigan Legislature, not this Court. *See Jacobson*, 197 U.S. at 30 ("It is no part of the function of a court or a jury to determine which one of two modes was likely to be the most effective for the protection of the public against disease. That was for the legislative department to determine in the light of all the information it had or could obtain.").

State Defendants specifically address only one other Plaintiff argument; that the Court lacks authority to consider the exhibits to their Motion to Dismiss.

I. Given the jurisdictional questions and wide-ranging scope of Plaintiffs' Complaint, the Court is authorized to consider State Defendants' exhibits under the standards for a Rule 12(b)(1) and 12(b)(6) motion.

Plaintiffs' Response continues to question State Defendants' exhibits (R. 45, Pl.'s Resp. Brf., Pg. ID# 708-09), even though Plaintiffs' 34-page Complaint attaches 18 exhibits of its own (some overlapping with State Defendants' exhibits or taken from the same websites) and refers to an expansive range of NBS-related topics, including:

- Plaintiffs' selective view of how the NBS program works;
- Allegations that stored dried blood spots (but not the Plaintiffs') have been used for "law enforcement purposes," which really means a handful of spots have been used for crime-victim identification as described in Exhibit 6, p. 2 (R. 32-7, Pg. ID# 554) to State Defendants' Brief in Support;
- Allegations that stored dried blood spots (but not the Plaintiffs') have been "sold" to third parties, which really means a break-even administrative fee has been collected from researchers for approved research projects. (R. 26-10, 1st Am. Compl., Pg. ID# 362-63.)

Under these circumstances, the Court's authority to consider State Defendants' exhibits is beyond question.

First, State Defendants have raised Rule 12(b)(1) jurisdictional arguments based on governmental immunity and Plaintiffs' lack of standing. (*E.g.*, R. 32, Brf. in Support, Pg. ID# 505-11.) The Court's subject-matter jurisdiction depends on standing, see *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016), and immunity is likewise jurisdictional. U.S. Const. amend. XI; *Edelman v. Jordan*, 415 U.S.

651, 662–63 (1974). As explained in State Defendants’ Brief, when reviewing a motion to dismiss under Rule 12(b)(1), “the court is empowered to resolve factual disputes.” *RMI Titanium Co. v. Westinghouse Elec. Corp.*, 78 F.3d 1125, 1134 (6th Cir. 1996). Because the court’s “very power to hear the case” is at issue, a trial court “is free to weigh the evidence and satisfy itself as to the existence of” its jurisdiction. *Id.* at 1134. Specifically, “a trial court has wide discretion to allow affidavits, documents and even a limited evidentiary hearing to resolve disputed jurisdictional facts.” *Ohio Nat. Life Ins. Co. v. U.S.*, 922 F.2d 320, 325 (6th Cir. 1990). No presumptive truthfulness attaches to a plaintiff’s allegations, and disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims. *Id.* Plaintiffs have the burden of proof. *Id.*

Second, under Rule 12(b)(6), “[d]ocuments attached to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff’s complaint and are central to the plaintiff’s claim.” *Jackson v. Cty. Of Columbus*, 194 F.3d 737, 745 (6th Cir. 1999), *overruled in part on other grounds by Swierkiewicz v. Sorema N.A.*, 534 U.S. 506 (2002). Moreover, “if a plaintiff references or quotes certain documents, or if public records refute a plaintiff’s claim, a defendant may attach those documents to its motion to dismiss” without converting it into a motion for summary judgment. *KBC Asset Mgmt. N.V. v. Omnicare, Inc.*, 769 F.3d 455, 466 (6th Cir. 2014); *see also Gavitt v. Born*, 835

F.3d 623, 640 (6th Cir. 2016) (a court deciding a Rule 12(b)(6) motion to dismiss “may consider exhibits attached to the complaint, public records, items appearing in the record of the case, and exhibits attached to defendant's motion to dismiss, so long as they are referred to in the complaint and are central to the claims contained therein, without converting the motion to one for summary judgment.”).

The Sixth Circuit has “taken a liberal view of what matters fall within the pleadings for purposes of Rule 12(b)(6). . . . [I]f extrinsic material merely ‘fills in the contours and details’ of a complaint, they add nothing new and may be considered without converting the motion to one for summary judgment.”

Armengau v. Cline, 7 F. App'x 336, 344 (6th Cir. 2001) (citing *Yeary v. Goodwill Industries-Knoxville, Inc.*, 107 F.3d 443, 445 (6th Cir. 1997)). “Fairness and efficiency require this practice” because “[w]ere courts to refrain from considering such documents, complaints that quoted only selected and misleading portions of such documents could not be dismissed . . . even though they would be doomed to failure.” *KBC Asset Mgmt. N.V.*, 769 F.3d at 466; *Gavitt*, 835 F.3d at 640. State Defendants’ exhibits fall precisely within these parameters. Plaintiffs’ Complaint provides their one-sided, embellished view of the NBS program, and State Defendants’ exhibits provide the Court a full description of the program.

Third, Federal Rule of Evidence 201 authorizes the court to take judicial notice of adjudicative facts, which courts have determined include “[p]ublic

records and government documents available from reliable sources on the internet,’ such as websites run by governmental agencies.” *Nikolao v. Lyon*, 238 F. Supp. 3d 964, 977 (E.D. Mich. 2016), *aff’d in part, vacated in part on other grounds*, 875 F.3d 310 (6th Cir. 2017) (citations omitted); *U.S. ex rel. Dingle v. BioPort Corp.*, 270 F. Supp. 2d 968, 972 (W.D. Mich. 2003) (same).

CONCLUSION AND RELIEF REQUESTED

Plaintiffs’ First Amended Complaint fails jurisdictionally and on the merits. Therefore, Defendants Michigan Department of Health and Human Services, Nick Lyon, Dr. Sandip Shah, Sarah Lyon-Callo, and Mary Kleyn respectfully request that this Honorable Court grant their Motion to Dismiss under Rule 12(b)(1) or 12(b)(6), and dismiss, with prejudice, all claims against them.

Respectfully submitted,

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Dated: August 1, 2018

CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2018, I electronically filed the above document(s) with the Clerk of the Court using the ECF System, which will provide electronic copies to counsel of record.

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